





Naval School of Health Sciences  
8901 Wisconsin Avenue  
Bethesda, Maryland 20889-5611

This Quality Manual sets forth the quality system policies and defines compliance with the ISO 9001:2000 requirements.

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## Document Review & Concurrence

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## 1.0 Scope

### 1.1 General

This quality manual describes the Naval School of Health Sciences, Bethesda (NSHS) Quality Management System (QMS) and how NSHS:

- a) Demonstrates its ability to consistently provide products/services that meets customer and applicable regulatory requirements, and
- b) Aims to enhance customer satisfaction through the effective application of the QMS, including processes for continually improving the system and assuring conformity to customer applicable regulatory requirements.

### 1.2 Application

The QMS applies to all NSHS functional elements. NSHS detachments are not covered under the QMS. Examples of the standard's applicability are given throughout this quality manual. Exclusions to specific elements are also noted.

## 2.0 Command Overview

### 2.1 Naval School of Health Sciences, Bethesda History


*The school was born out of a need to provide specialists in hospital and medical administration during World War II. On 3 July 1942, a course of instruction was established within the Naval Hospital, Bethesda, Maryland, now the National Naval Medical Center, to provide general hospital management training for Warrant Officers and temporary Hospital Corps Officers. The course continued as part of the training department of the Naval Hospital Corps Officers School until 1945.*

*On 2 August 1945 the Hospital Corps Officers School was disestablished. At that time, the Naval School of Hospital Administration was created by the authority of the Secretary of the Navy, with a Hospital Corps Officer-in-Charge. The title of Hospital Corps Officer-in-Charge was subsequently changed to Medical Service Corps Officer-in-Command, and eventually to Commanding Officer.*

*On 18 March 1970 the school was redesigned as the Naval School of Health Care Administration.*

*On 1 October 1977 the school underwent a major reorganization. On that date, the Command was designated as the Naval School of Health Sciences (NSHS), Bethesda, Maryland. Included within the new Command were the following component units, each under an Officer-in-Charge:*

- *Naval School of Health Sciences, Bethesda Detachment, Naval Undersea Medical Institute, Groton, Connecticut*
- *Naval School of Health Sciences, Bethesda Detachment, Portsmouth, Virginia*
- *Naval School of Health Sciences, Bethesda Detachment, Academy of Health Sciences, Fort*

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Sam Houston, Texas

*This reorganization brought vast changes in the mission and capabilities of the Command. The school assumed the task of providing both technical and managerial training to meet identified needs of the Navy Medical Department. For the first time, the school was able to offer courses to students in all Medical Department Corps' ranging from entry-level technical training to advanced management training.*

*In February 1981 the NSHS Bethesda detachment at Gorgas, Panama was established to provide instructional and administrative support to the Navy's Tropical Medicine course offered at that location and in June, 1989 that detachment was transferred to San Juan, PR.*

*On 1 October 1981 all audio-visual services located on the Naval Medical Command National Capital Region complex were consolidated into the NSHS Biomedical Communication Center. The Biomedical Communication Center was charged with operating all Navy Medical Department audio-visual facilities located within the National Capital Region.*

*On 1 October 1989 the Naval School of Health Sciences, Bethesda, Detachment USAMEOS, Aurora, CO was established to provide training to naval personnel in the field of Biomedical Equipment Repair/Maintenance.*

*On 1 October 1994 the audio-visual services were transferred to the National Naval Medical Center, Bethesda, Maryland.*


*On 1 October 1995 Naval School of Health Sciences, Bethesda assumed duties and responsibilities as an Echelon III command after the disestablishment of the Naval Health Sciences Education and Training Command (HSETC). The Naval School of Health Sciences, Portsmouth, VA assumed the duties and responsibilities as an Echelon III command with the Naval School of Health Sciences, Groton, CT as a detachment. The Naval School of Health Sciences, Aurora, CO and the Naval School of Health Sciences, Fort Sam Houston, TX became detachments of the Echelon III Naval School of Health Sciences, San Diego, CA.*

*On 1 October 1996 the audio-visual services were transferred back to NSHS, Bethesda as one of the directorates within the Command.*

*Every year, thousands of students are trained at NSHS schools around the country in order to provide the physicians, nurse anesthetists, physicians assistants, technicians, managers, and other health professionals needed to meet the Navy's operational mission.<sup>1</sup>*

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<sup>1</sup> NSHS Command History Archives

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## 2.2 Command Relationship, Mission and Functions

1. Status. The NSHS is an echelon III field activity in an active operating status under a Commanding Officer.
2. Command and Support. NSHS is under the command and support of the Chief, Bureau of Medicine and Surgery (BUMED).
3. Area Coordination. NSHS is subject to the area coordination authority of the Commandant, Naval District Washington, DC.
4. Functions. As directed by BUMED:
  - a. Conduct enlisted technical training, manage and conduct professional and management training for assigned DOD personnel.
  - b. Provide program management for selected Medical Department education and training programs. Management responsibility includes: identifying training requirements; developing long/short-range plans; directing development and periodic review of new programs; approving curricula; assuring efficient and effective use of resources; assuring compliance with law, regulation, and guidance from higher authority; maintaining liaison with DOD and civilian training organizations and professional and accrediting bodies; approving continuing education programs; funding authorized board certification examinations; and funding continuing education for personnel attached to non-claimancy 18 commands. Programs managed are
    - (1) In-service and out-service programs, continuing education and board certification for Medical Service Corps, Medical Corps, Dental Corps, and Nurse Corps Navy officers,
    - (2) Hospital Corpsman and Dental Technician inservice selection programs and continuing education,
    - (3) Joint Medical Executive Skills Development Program (JMESDP),
    - (4) Clinical Investigation Program (CIP), and
    - (5) Armed Forces Health Professions Scholarship Program (AFHPSP).
5. Provide consolidated educational support functions for student selection, admission, and registration for courses and programs.
6. Conduct conferences, seminars, symposia, and workshops.
7. In keeping with the specific needs of the naval service, plan for and provide education and training for health care personnel at the technical, undergraduate, graduate, doctoral, and postdoctoral levels.

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8. Provide appropriate continuing education programs for Navy Medical Department personnel.
9. Provide visual information services for Navy Medicine and other agencies as requested.
10. Where possible, develop and provide appropriate training programs for Naval Reserve Medical Department personnel.
11. Provide administration and management for operational and readiness training programs for the Navy Medical Department.
12. Provide Registrar functions for the Navy Medical Department.
13. Perform additional functions as may be authorized or directed by higher authority.

The Command is assigned approximately 180 personnel and is classified under SIC Code \*80 and \*874.

## 2.3 Mission, Vision, and Values

### Mission

We provide education, training, information, and program management in health care delivery to enable uniformed services personnel to meet their mission in war and peace.

### Vision

The Naval School of Health Sciences, Bethesda is the pacesetter in continuous learning and guidance for the health care professions, reaching customers worldwide through the innovative use of appropriate technology. We accomplish this as a high performance organization that is responsive to ever-changing customer needs and mission requirements.

### Values


- We support the Navy Core Values: Honor, Courage, and Commitment.
- We **HONOR** the promises we make.
- We have the **COURAGE** to do the right thing.
- We are **COMMITTED** to professionalism and teamwork.
- We provide **QUALITY** in all we do.

## 3.0 Glossary of Terms

**Contract:** An accepted order from the customer for services, materials, or information.

**Controlled Document:** Any document that is reviewed and approved before release for use or reference.



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**Customer:** The recipient of a product/service provided by the organization.

**Customer-Centered Enterprise:** An organization that believes that the customer is the reason for its existence. This organization knows its customer, knows what the customer wants, and how the customer wants it. The organization constantly measures customer satisfaction and focuses on delighting the customer.

**Customer Satisfaction:** The way a customer wants or expects to be treated and how he/she perceives the actual treatment.

**Customer Service:** The art of doing all that is necessary to enhance the customer's satisfaction.

**Directorate Processes:** Those processes that can essentially be performed by personnel from one specific Directorate.

**Document:** Something serving as proof or evidence.

- Controlled Document: Authority or ability to regulate, direct, or influence.
- Uncontrolled Document: Not having authority or ability to regulate, direct or influence.

**Effectiveness:** Doing the right things. A performance dimension addressing the degree to which the intervention is provided in the correct manner, given the current state of knowledge, in order to achieve the desired/projected outcome.

**Efficiency:** Doing things right. A performance dimension addressing the relationship between the outcomes (results of the intervention) and the resources used to deliver care. The ultimate measure of efficiency is the relationship between the cost of achieving a goal to the benefit achieved by that goal.

**High Performance Organization:** Groups of employees who produce desired goods and/or services at higher quality levels with the same or fewer resources and in a shorter time. Their productivity, timeliness, and quality improve continuously from day to day, week to week, and year to year, leading to the achievement of their mission.

**Inter-Directorate Processes:** Those processes that are under the operational responsibility of two or more directorates.


**Master Document List:** A list of processes located on the NSHS ISO Server Directory or website. The list consists of the table of contents for both directorate and inter-directorate processes.

**Note:** A brief informal message, comment, or explanation.

**Organization:** Naval School of Health Sciences, Bethesda.

**Product:** The result of NSHS activities or processes (i.e. courses, training materials, instructions, etc.). As used in this manual, it can also include the concept of service.



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**Purchase:** Any contract placed with a supplier for goods or services.

**Supplier:** An organization that provides goods/services to NSHS.

**Values:** The underlying concepts that form the belief and behavior base for an individual or organization. (NSHS Strategic Plan)

### Acronyms:

**BUMED** – Bureau of Medicine and Surgery

**DOD** - Department of Defense

**ESC** - Executive Steering Council

**FAR** - Federal Acquisition Regulation

**NMCOD** - Navy Medicine Center for Organizational Development

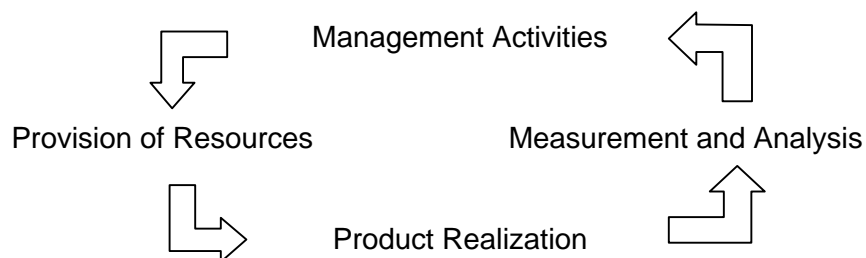
**NSHS** - Naval School of Health Sciences, Bethesda


**QMS** – Quality Management System

## **4.0 Quality Management System**

### **4.1 General Requirements**

This Quality Manual describes the NSHS quality system and how we implement it to ensure our products/services meet or exceed requirements. This manual includes and/or makes reference to the quality system processes and outlines the quality system documentation structure. The sequence of NSHS processes is reflected through the alignment with ISO standards, as depicted below:



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This Quality Manual addresses management activities (section 5), provision of resources (section 6), product realization (section 7), and measurement, analysis and improvement (section 8). Process interaction is reflected within each process flow chart.

## 4.2 Documentation Requirements

### 4.2.1 General

Our QMS describes Quality Policy (5.3), Quality Objectives (5.4.1), policies, processes and systems used to ensure quality in our products/services and how they are implemented to ensure conformity to specified requirements. Our QMS includes documented procedures required by ISO 9001:2000.

Supplementing our QMS are many instructions and policies that existed prior to ISO implementation. These are located on the network and can be accessed by all NSHS personnel. NSHS controls these documents per SECNAVINST 5225.1 series. Control of all QMS documents is maintained per NSHS-002.

### 4.2.2 Quality Manual

This Quality Manual establishes the scope of the QMS, which includes processes, work instructions, forms, and works aids. Each process internally describes interaction with other applicable processes.


Process owners are responsible for effectively implementing procedures necessary to meet QMS requirements. Procedure and work instruction detail depends upon the complexity of the work, methods used, and the skills and training needed by personnel to carry out the activity.

Process owners are responsible for training appropriate personnel to ensure proper process implementation.

Initial processes and quality records may be paper copy, electronic copy, or in other media as deemed appropriate (see 4.2.3). Once approved and incorporated into the NSHS Quality System, they become controlled documents and are maintained per 4.2.3 and 4.2.4 of the Quality Manual.

#### Hierarchy of QMS documents

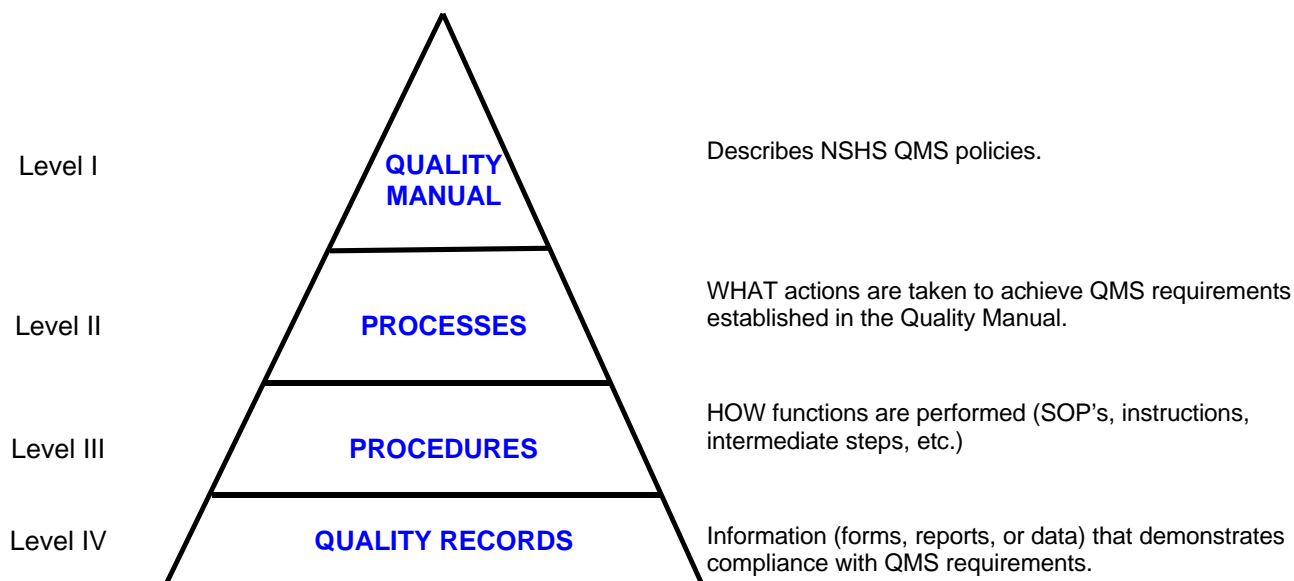
- Level I: The Quality Manual provides a general overview of the QMS and defines the quality policy. It corresponds to each of the ISO 9001:2000 standard elements.
- Level II: Inter-Directorate and Directorate processes. The processes define who is responsible for the activity, discuss interrelationships between different NSHS directorates, list the quality records of the defined process, and describe the closed loop systems that ensure quality measurements are reported to individuals responsible for improving the QMS.
- Level III: Work procedures and SOP's provide more detailed directions for executing activities of level II processes. Each process owner determines whether to create a procedure to support a

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level 2 process or to control the process through documented on-the-job training.

- Level IV: This level of data/documents includes forms, charts, checklists, reports, quality records, and other evidence which demonstrate conformance to specified requirements, and may be an addendum or attachment to a specific process.

### ISO 9001:2000 QUALITY SYSTEM STRUCTURE




#### 4.2.3 Control of Documents

QMS documents may be initiated by anyone assigned to NSHS and are issued after review and approval by authorized personnel. Document changes are reviewed and authorized by the same reviewer or directorate/department that issued the original document, unless specific alternate authority is identified (see NSHS-004). The designated reviewer or director/department has access to pertinent background information upon which to base their review and approval. The nature of the change is identified in the document or attachments.

Relevant versions of Level I & II processes are maintained electronically on the NSHS intranet. The Management Representative maintains the original Quality Manual and Level II processes. Printed Level I & II documents may be made available to users and other interested parties on appropriate occasions (i.e. training) with the understanding that these documents are UNCONTROLLED. After use, obsolete documents are destroyed to prevent inappropriate use. Any UNCONTROLLED documents retained for legal or knowledge preservation purposes are suitably identified per SECNAVINST 5212.1 series.

We control external documents such as higher authority directives by requiring each user to verify the current version prior to performing process steps. Required external documents are listed as references within QMS processes, and may be in any type of hard copy or electronic media.

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Control of documents is outlined in NSHS-002. This process establishes requirements:

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use, and
- e) to ensure that documents remain legible and readily identifiable.

#### 4.2.4 Control of Quality Records

Quality records are specific documents (hard copy, electronic, or other media) referred to in this QM or level II processes and retained to demonstrate compliance with NSHS QMS requirements. Process owners are responsible for maintaining their quality records and ensuring those records are legible, readily identifiable and retrievable.

Each NSHS QMS process addresses the identification, collection, indexing (filing), storage, retention period, and disposition of quality records.

Quality records are made available for evaluation by staff, customers, and other interested parties. This is based on their desires and the appropriateness of making these records available based on existing laws, policies, etc.


### 5.0 Management Responsibility

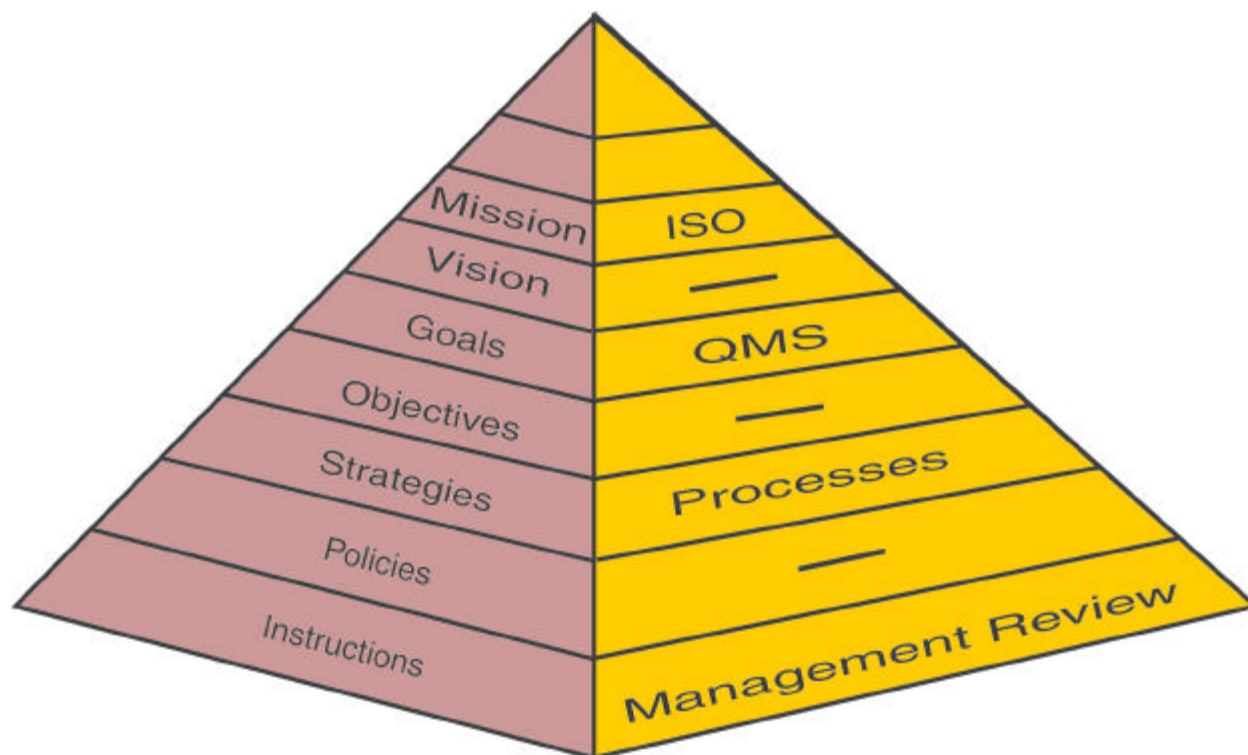
#### 5.1 Management Commitment

NSHS is committed to developing, implementing, and continually improving the effectiveness of our QMS. The Command accomplishes this by effectively distributing available resources, and communicating to staff in several formats the importance of meeting customer, statutory, and regulatory requirements, ensuring that NSHS meets Command goals and objectives.

The NSHS quality policy communicates the Command's organizational goal(s) in pursuit of understanding and satisfying customer expectations. NSHS quality policy and quality objectives are implemented in our Strategic Plan.

Management also meets during the year to review progress and adjust resources as needed to ensure Command viability.

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The pyramid illustrates the relationship between the Strategic Plan and the Quality Management System. The QMS supports, overlaps, interfaces, and parallels the Strategic Plan. Implementing ISO is one part of our Strategic Plan (Best Business Practices). Both support from the bottom up to contribute to our mission.


## 5.2 Customer Focus

NSHS is committed to being a customer-centered enterprise by:

- Achieving excellent service through customer-focused staff,
- Incorporating customer input and feedback into the design and delivery of all our products and services,
- Using appropriate technology to provide optimal customer service, and
- Ensuring customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction.

## 5.3 Quality Policy

*NSHS is the pacesetter in continuous learning and guidance for the healthcare professions, reaching customers worldwide through the innovative use of appropriate technology. We accomplish this as a high performance organization that is responsive to ever-changing customer needs and mission requirements.*

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NSHS is committed to comply with QMS requirements and continually improve the quality management system. The Executive Steering Council (ESC) meets to review and revise (as necessary) the quality policy, Strategic Plan, and Annual Plan. These are communicated to all staff at Command orientation and at periodic training.

## 5.4 Planning

### 5.4.1 Quality Objectives

NSHS management ensures that the quality policy, goals, and related objectives from the Strategic Plan are established at relevant functions and at all Command levels. Objectives development will incorporate findings from management review, environmental assessments, and current performance. The objectives are measurable and consistent with the quality policy.

### 5.4.2 Quality Management System Planning

The ESC reviews the QMS at least annually. QMS integrity is maintained when changes are planned and implemented per NSHS-002.

## 5.5 Responsibility, Authority and Communication

### 5.5.1 Responsibility and Authority

The current version of NSHSBETHINST 5450 indicates the responsibility, level of authority, and the interrelationship of NSHS staff.


#### Commanding Officer, Code 00

The Commanding Officer is responsible for the Command organization and management to accomplish the NSHS mission as efficiently and effectively as possible. Subject to the orders of higher authority, the Commanding Officer exercises complete military jurisdiction within the Command and is responsible for the safety and well being of the entire Command. The duties of the Commanding Officer are prescribed in Navy Regulations and the Manual of the Medical Department.

Through the Chief, BUMED, the Commanding Officer provides professional direction, guidance, and supervision of education and training.

The Commanding Officer may, when not contrary to law or regulations, delegate duties to other subordinates to the maximum extent consistent with retention of control. Such delegation of authority, however, shall in no way relieve the Commanding Officer of continued responsibility for the safety, well being, and efficiency of the entire Command.



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### **Executive Officer, Code 0X**

The Executive Officer is the direct representative of the Commanding Officer in coordinating NSHS internal administration. All Executive Officer orders are regarded as emanating from the Commanding Officer and govern all persons within the Command. The Executive Officer is responsible, under the Commanding Officer, for the performance of duty and good order and discipline of the Command.

### **Command Master Chief, Code 0CMC**

The Command Master Chief is the special advisor and special assistant to the Commanding Officer in all matters pertinent to the welfare, job satisfaction, morale, utilization, and training of enlisted members. The Command Master Chief:

- Maintains and promotes the effectiveness and efficiency of the chain of command.
- Advises the Commanding Officer regarding policy formulation or change pertaining to enlisted members.
- Ensures that policies are explained, understood and carried out by subordinates through basic leadership principles.
- Helps prepare for and participates in enlisted ceremonies.
- Attends and/or represents the Command at official functions, inspections, and conferences.
- Serves on boards and committees as appropriate.
- Performs other functions as described in instructions and regulations or as assigned by the Commanding Officer.


### **Executive Steering Council, Code 0ESC**

The Executive Steering Council (ESC) is the Command's principal leadership team. Composed of senior representatives from the Command military and civilian communities, the ESC will act as the primary advising/consulting body to the Commanding Officer. The ESC is empowered to perform strategic and annual planning, policy formulation, resource oversight, and chartering such groups as necessary to carry out the mission of the Command. All ESC decisions have direct linkage to the Command Strategic Plan, mission, vision, goals and objectives.

### **Navy Medicine Center for Organizational Development, Code 0NMCOD**

The Navy Medicine Center for Organizational Development (NMCOD) is administratively assigned to NSHS as a detachment, but operates independently under BUMED auspices. They provide consultation, coaching, and training in strategic change and continuous performance improvement in organizations. NMCOD serves as BUMED's consultative branch for organizational performance improvement, and interfaces regularly with headquarters staff and the subordinate commands to facilitate organizational performance improvement efforts. The products and services of NMCOD are aligned with its purpose, which is to promote optimal organizational performance throughout all Navy Medicine activities.



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## Director of Academics, Code 0A

The Director of Academics provides education and training programs for Navy Medical Department personnel. The Directorate includes the following departments: Registrar, Management and Specialty Training, Command Education and Training, Student Support and Academic Program Management. The Academic Director:

- Ensures collaborative relationships to provide an environment that promotes the educational, professional, and personal growth of staff and students.
- Supervises the establishment and implementation of academic standards.
- Acts as curriculum approval authority for designated non-technical courses.
- Ensures development of annual training plans for directorate personnel.
- Develops and executes the directorate Operating Target (OPTAR) budget.
- Serves as liaison to the Center of Excellence for Remote and Medically Under-Served Areas (CERMUSA).
- Leads the continuous planning, execution and follow-up of the directorate mission to support the Command Strategic Plan.


## Director of Finance, Code 0F

As Comptroller, the Director of Finance reports directly to the Commanding Officer through the Executive Officer, and serves as the principal staff advisor to the Commanding Officer in the interpretation of guidance from higher authority to effectively direct, manage, and coordinate the provision of financial and resources; assists the Commanding Officer in monitoring the economic and efficient management of education and training programs; advises and assists the Commanding Officer in responding to higher authority concerning budgets and the execution of education and training resources and maintains liaison with BUMED and advises operating target managers of the status and availability of operating funds. The Director of Finance:

- Keeps the Commanding Officer apprised of Command financial status, funds availability, and related financial matters.
- Informs and advises the ESC regarding the financial status and availability of Command operating funds and economic and efficient operations.
- Prepares budgetary and financial exhibits in response to BUMED budget, annual financial plan, midyear calls and for other budget reviews and submissions.
- Reviews and makes recommendations to the Commanding Officer on the Command's budget submissions, financial reports, annual financial plans, and requests for additional operating funds.
- Ensures adequate internal and management controls to safeguard resources.


## Director for Medical Corps Professional Programs, Code 0M

The Director for Medical Corps Professional Programs directs and oversees the execution of Graduate Medical Education (GME) programs for the Navy Medical Corps to ensure that the proper mix and number of specialists are trained each year to meet the requirements of the Navy

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Medical Department. Monitors and supports Full-Time Inservice (FTIS) internship, residency and fellowship programs and manages the Full-Time Outservice (FTOS), Other Federal Institution (OFI), Navy Active Duty Delay for Specialists (NADDS), One Year Delay, and Financial Assistance Programs (FAP). Manages the annual GME selection process, conducts the Navy GME Selection Board, and coordinates Navy participation in the annual Joint Service GME Selection Board. Plans and conducts periodic Medical Education Policy Council (MEPC) meetings and monitors implementation of recommendations; Provides liaison with medical school students in matters of professional development and provides central management of Continuing Medical Education (CME) for Medical Corps officers. The Director performs the following functions:

- Provides advice and recommendations to the Surgeon General, Chief of the Medical Corps, and other interested parties regarding policies and priorities for GME programs.
- Monitors annual Medical Corps Training Plan execution.
- Develops and disseminates information on GME programs, policies, statistics, guidance and activities.
- Serves as point of contact for Medical Corps personnel on GME opportunities and coordinates solutions to individual special issues.
- Coordinates planning and implementation of the annual Joint Service GME Selection Board with GME officials in the Office of the Assistant Secretary of Defense for Health Affairs (OASD (HA)) and GME offices of the Army and Air Force.
- Coordinates with Chief of the Medical Corps for special GME selections necessary due to selectee declinations, changes in trainee status, and other situations resulting in vacancies.
- Maintains close liaison with Chief of the Medical Corps, other BUMED officials and Specialty Leaders, Navy GME Directors at Navy teaching hospitals, the Navy Personnel Command (NPC), and other Navy and DOD organizations to plan and implement program activities.
- Analyzes program issues, develops issue papers, prepares recommendations for MEPC and Surgeon General consideration, and participates in GME planning.
- Serves as liaison with OASD (HA), Army, Air Force, Public Health Service, the Uniformed Services University of Health Sciences and NPC regarding GME policies, issues and programs.
- Interacts with academic institutions, professional organizations, accrediting bodies, and civilian GME oversight agencies to ensure programs and policies are in compliance with requirements and to follow national trends in GME.
- Coordinates accessions and recalls for Navy sponsored GME.
- Reviews requests and makes recommendations regarding Oversees planning for MEPC meetings, agenda development, coordination and review of issues, and preparation of policy recommendations for Surgeon General's approval, and monitors progress of implementing decisions.
- Coordinates selection of inservice GME program directors.
- Participates in joint service GME planning for program integration, affiliation, realignments, and other military GME issues.
- Writes, as primary author, BUMED instructions and notices concerning Medical Corps education and training programs.

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### Director for Program Management, Code 0P


The Director, Program Management oversees and directs all program management functions with the exception of Medical Corps Professional Programs and the Armed Forces Health Professions Scholarship Program and serves as the principal advisor to the Commanding Officer on all program management issues and promotes cost effective management of Navy Medicine's medical department officer civilian education programs. The Director performs the following functions:

- Directs all program management activities under his/her cognizance.
- Directs and oversees development and execution of directorate budget.
- Ensures consistent and equitable application of policy applicable to all corps program management functions.
- Provides advice to the Commanding Officer on all aspects of program management.

### Director for Support Services, Code 0S

The Director, Support Services provides oversight and direction for the Armed Forces Health Professions Scholarship Program (AFHPSP), materials management, and a full range of administrative, disciplinary, and managerial support for staff and student personnel. The Support Services Directorate consists of the AFHPSP Department, Materials Management Department and Administrative Services Department with Administrative, Management Information, Manpower/Personnel and Operating Management Divisions. The Director, Support Services is responsible for the following functions:

- Maintains oversight and control of the AFHPSP.
- Ensures material readiness of Command while implementing adequate internal and management controls to safeguard resources.
- Serves as the principal advisor to the Commanding Officer, Executive Officer, Directors, and Department Heads for all matters related to Command personnel management.
- Provides administrative and organizational guidance in all administrative management matters including general administration, civilian and military personnel administration, legal and disciplinary proceedings, correspondence management, Command organization, record maintenance, and recurring reports.
- Manages the Command's Facilities Maintenance, Physical and Personnel Security, Key and Lock Control, and Disciplinary/Legal Support Programs.
- Coordinates civilian personnel actions between NSHS and Human Resource Office-Washington (HRO-W).
- Prepares and reviews position descriptions and performance standards; prepares the SF-52 and other documentation relevant to civilian personnel actions; coordinates requests for recruiting and hiring for vacant positions and establishes deadlines with supervisors, hiring authority, and HRO-W.
- Responsible for civilian personnel training, orientation, and coordination of civilian personnel information between staff and the Human Resources Office. Maintains tracking system for personnel actions, correspondence and training.


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## Director for Visual Information, Code 0V

The Director for Visual Information (VI) provides oversight and direction for the management of Navy Medicine's visual information and training technology programs. Providing expertise on visual information and training technology, the Director serves in an additional duty relationship to the Chief, Bureau of Medicine and Surgery as Code 05B2, Special Assistant for Visual Information. In this capacity, the Director is responsible for the BUMED Major Claimant Visual Information Management Office (MCVIMO), which serves as the approval authority for BUMED VI/AV programs and VI equipment management.

The Visual Information Directorate plans, controls, and manages all aspects of the Visual Information (VI)/Audiovisual (AV) programs in support of medical and dental imaging requirements. The Directorate produces and acquires all types of AV programs and media. The Directorate consists of the Medical Media Production, Medical Graphic Arts and Medical Photography Departments. The Visual Information Directorate responsibilities include, but are not limited to:

- Writing, as primary author BUMED (MED-05) instructions and guidance for implementing DOD and Navy imaging policy and procedures within the Naval Medical Department.
- Maintaining liaison with the BUMED, CNO, DOD, other Federal agencies as appropriate.
- Ensuring proper and effective use of VI resources throughout all BUMED commands and activities.
- Directing and managing the planning, development, and evaluation of medical educational media/training technology programs.
- Representing BUMED on the Tri-service Medical Review Board for Visual Information (TRIMRBVI); identifying potential joint interest requirements and serving as its chairman when chairmanship is rotated to the Navy.
- Monitoring the operation of all BUMED VI Support Centers (also known as Biomedical Communication Centers).
- Demonstrating the applications of emerging VI technologies in support of all Medical and Dental imaging requirements.
- Formulating and revising proposed BUMED policy regarding VI and VI/AV products.
- Providing expertise in VI techniques and procedures relative to Navy Medical Department education and training.
- Reviewing/identifying medical VI product/production requirements within BUMED's subordinate commands and activities; coordinating these services to prevent redundant development and excessive procurement, production, and distribution of medical VI products.
- Conducting annual reviews and periodic site visits to monitor and evaluate VI activities and functions; ensuring effective utilization of resources, and providing recommendations for corrective action.
- Representing BUMED VI interests at conferences and symposia sponsored by other DOD agencies, private industry and academia.
- Managing the development of linear and interactive VI productions for the Navy Medical Department.
- Advising on application of medical training technology for reserve programs.

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## All Staff

- Support the quality policy and the appropriate elements of the quality system for their areas of work.
- Dedicate efforts to the reduction, elimination and prevention of quality deficiencies.
- Initiate action to prevent the occurrence of non-conformities related to product/service, process, and quality system.

### 5.5.2 Management Representative

In support of the Commanding Officer, NSHS, the Management Representative oversees the overall NSHS QMS. The specific identity of the Management Representative is recorded in the Management Review minutes (5.6.1). The Management Representative:

- Ensures the quality system is established, implemented, and maintained per ISO 9001:2000.
- Evaluates and reports on the performance of the quality system to management for review and as a basis for improving the quality system.
- Reviews internal audit reports to verify the effectiveness of the quality system.
- Promotes awareness of customer requirements throughout the Command.

### 5.5.3 Internal Communication

NSHS will ensure appropriate communication processes are established and used throughout the Command, including e-mail, Plan of the Week, Captain's Calls, and 1MC (public announcement system). Periodic communication will take place regarding the effectiveness of the QMS, including publishing for all hands the meeting minutes.

## 5.6 Management Review

### 5.6.1 General


QMS reviews are held at least semi-annually to assess suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for QMS changes. The Commanding Officer chairs the Executive Steering Council (ESC) and is responsible for ensuring these meetings are conducted. He/she may delegate this responsibility as needed.

QMS activities/processes reviewed include, but are not limited to, the following:

- NSHS quality policy and objectives (5.3)
- Corrective and preventive actions (8.5.2)
- Registrar and internal audit results (8.2.2)
- Training plans and delivery effectiveness (6.2.2)

The Commanding Officer plans, prepares, schedules, communicates, and conducts the meetings. The Commanding Officer also prepares a structured agenda for each meeting. The Commanding



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Officer may delegate the above responsibility as necessary.

Minutes are recorded and when combined with 1) a copy of the agenda, 2) a list of assigned action items, and 3) any appropriate attachments, provide a quality record of such meetings. If corrective actions are necessary, they are submitted as Corrective Action Reports for action, implementation, and tracking.

Management review records are approved by the Commanding Officer and retained in chronological order by the Management Representative for three years, and then destroyed.

### 5.6.2 Review Input

The input to management review includes the following:

- Continuous improvement initiatives.
- Corrective and preventive actions.
- Customer feedback and enhancements.
- Customer satisfaction surveys.
- Follow-up to previous management review activities.
- Internal and external audit results.
- Process performance.
- Product quality data.
- Review of quality policy and objectives against the Command objectives.
- Planned changes that could affect the Quality Management System.

### 5.6.3 Review Output


The output from management review activities includes decisions and actions related to:

- Improving the effectiveness of the quality management system.
- Improving the product related to customer requirements.
- Resource needs.

## 6.0 Resource Management

### 6.1 Provision of Resources

The Commanding Officer and the ESC will ensure adequate resources to implement and continually improve the QMS, and enhance customer satisfaction. Resources are allocated to the right place at the right time to support the QMS. Directors have the responsibility to 1) train their staff, 2) execute their budget, and 3) enhance quality of work life.

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## 6.2 Human Resources

### 6.2.1 General

Documented level two processes outline the requirements for identifying training needs and providing training for personnel who perform activities that affect quality. Personnel performing specific tasks are qualified on the basis of appropriate education, training, and/or experience, as required.

Effective with the initial issue date of this Quality Manual, all current NSHS personnel are considered fully qualified to perform their jobs based on past successful completion of assigned tasks.

Qualification of new personnel and/or transfers of NSHS personnel between directorates are accomplished by training in appropriate inter-directorate and directorate processes and applicable NSHS instructions.

Directors are responsible for determining which inter-directorate and directorate processes are to be trained to which individuals as required by their duties and responsibilities. A training matrix is to be developed, maintained, and retained within each directorate to provide summary evidence of the requirements and training completion status for all directorate personnel. The Command Education and Training Officer will maintain training records.

### 6.2.2 Competence, Awareness and Training

Our processes identify training needs and NSHS provides appropriate training to all staff performing activities affecting the QMS. Training is strategically linked to the daily operation of NSHS.

Training effectiveness is periodically reviewed by various methods, such as trainer questionnaires, audits and appraisals on a periodic basis.


## 6.3 Infrastructure

Since education/training, program management and support/services are the primary NSHS product lines, an appropriate classroom and office environment is maintained at all times.

Electronic peripherals (i.e. computers, fax machines, modems, copiers, printers, projectors) are the primary equipment used to accomplish defined objectives and strategies. NSHS is continually upgrading the quality of work life for staff and students.

At the present time there are no special processes at NSHS that would require operator qualification or enhanced process monitoring. Should special processes be necessary in the future, NSHS will address each appropriately and comply with all requirements of 6.3 of ISO 9001:2000.



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## 6.4 Work Environment

Premises are maintained in a state of order, cleanliness and repair to ensure product/service conformity and consistency by means of scheduled inspections and appropriate directives.

## 7.0 Product Realization

### 7.1 Planning of Product Realization

Strategic and tactical (annual) quality planning is largely described in the NSHS Strategic Plan and evident through its implementation. This plan is reviewed annually. The portions of quality planning not addressed in this plan and identified by ISO standard numbering are:

- Inspection and verification points are identified and documented during the design and creation of NSHS products/services.
- Any changes to the standards of acceptability are clarified whenever workmanship standards are changed.
- The identification of quality records occurs as processes are developed or modified or when business activities change. Quality records are appropriately identified in the processes.

If existing processes cannot fulfill a particular project or customer request, project specific plans are created to insure the specified requirements are met. These plans are consistent with all other requirements of the QMS and are required when a significant change to an existing service, process, inspection, verification, resource requirement or skill is required to meet a specific request for service, projects, or contracts.

NSHS promotes internal awareness of safety considerations relative to its products/services through process control as it applies.

Control Plans are developed for selected products/services that require the use of more complex design and production considerations. A determination is made during the development phase whether control plans will be developed. Control Plans provide appropriate information regarding production, inspection, equipment, etc.


### 7.2 Customer-Related Processes

#### 7.2.1 Determination of Requirements Related to the Product/Service

Procedures exist for reviewing customer requirements and for coordinating review activities to ensure customer requirements and amendments to these requirements are communicated in a controlled manner.

The procedures require appropriate generation and review of each proposal, contract, or order to ensure:

- Customer requirements and contract scope are adequately defined and documented including

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verbal specifications.

- Possible contingencies or risks are identified and included as appropriate.
- Proprietary information is adequately protected.
- Adequate definition of the responsibilities of both NSHS and our customer(s), including requirements specification, installation, acceptance, and related support activities.
- Statutory and regulatory requirements related to the product/service are clarified.
- Delivery and post-delivery requirements are specified.
- The product/service is deliverable.

### 7.2.2 Review of Requirements Related to the Product/Service

NSHS reviews the requirements related to products/services before committing to supply the product/service considering the following:

- NSHS has the capability to meet the contract or accepted order requirements.
- Possible contingencies or risks are considered.
- Appropriate functional areas participate in the review process.
- Order and/or amendment approval is defined.
- Records of order reviews are maintained.
- Customer requirements, verbal and written, are documented and confirmed prior to acceptance.
- Any accepted customer requirements that differ from those in the original request are resolved, documented, and acknowledged by the customer.

Amendments, extensions or other requests are documented, agreed to by both parties, and conveyed to the concerned functions within NSHS per documented procedures.


Where the customer provides no documented statement of requirements, the customer requirements are confirmed before acceptance.

### 7.2.3 Customer Communication

NSHS maintains continued communication with the customer before, at, and after contract closure. Customer communication includes product information, handling customer complaints, inquiries, references, etc.

## 7.3 Design and Development

The appropriate directorate will accomplish design and development of new products/services. The Director(s) will be responsible to assign and coordinate qualified personnel to plan and execute projects. Previous design information is used as appropriate for similar projects.

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### 7.3.1 Planning

The design or development of a product/service will begin by determining:

- The responsibilities and authorities for design and development.
- The design and development stages.
- The review, verification and validation appropriate to each design and development stage.

NSHS will manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output will be updated, as appropriated, as the design and development progresses.

### 7.3.2 Inputs

Inputs relating to product/service requirements are determined and recorded. Inputs include:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Information derived from previous similar designs, where applicable, and other requirements essential for design and development.
- Incomplete, ambiguous, or conflicting requirements are resolved.

These inputs will be reviewed for adequacy. Requirements will be complete, unambiguous and not in conflict with each other.

### 7.3.3 Outputs

The outputs of design and development provided in a form that enables verification against the design and development input and will be approved prior to release.


Design and development outputs include:

- Meeting input requirements.
- Providing appropriate information for purchasing, production and service provision.
- Containing or referencing product/service acceptance criteria.
- Specifying product/service characteristics essential for safe and proper use.

### 7.3.4 Review

At suitable stages systematic reviews of design and development are conducted. This consists of:

- Evaluating the ability of design results to meet requirements.
- Identifying any problems and proposing corrective action.

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Participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Records of reviews, results and any necessary actions will be maintained.

### 7.3.5 Verification

Verification activities are performed to ensure design outputs have satisfied design inputs requirements. Verification records are maintained.

### 7.3.6 Validation

Design and development validation, where necessary, will be performed according to planned arrangements. Products/services designed by NSHS include curriculum and video products. During design, these items will be verified with customers and/or stakeholders to ensure that the designed product is capable of fulfilling the requirements for the specified or known intended use or application. Identified problems and their potential impact will be noted and tracked.

### 7.3.7 Changes

Design and development changes will be identified and recorded. The changes are reviewed, verified, validated as appropriate, and approved before implementation. The review of design and development changes shall include evaluating the effect of the changes on components and delivered products.

## 7.4 Purchasing


### 7.4.1 Purchasing Process

Purchasing documents clearly and completely identify ordered materials, precision equipment, or other required resources. Purchasing documents are completed to clearly define the material requirements and may include reference to applicable drawings, inspection instructions, and other relevant technical data, including the QMS standard to be applied to the product/service when applicable. All purchasing data is reviewed for accuracy and completeness, and then approved for release to suppliers.

NSHS will evaluate and select suppliers based on their ability to supply the product/service in per our requirements. Criteria for selection, evaluation and re-evaluation will be established. Records of evaluation results and any necessary actions arising from the evaluation will be maintained.

### 7.4.2 Purchasing Information

Procedures are established and maintained to ensure products/services purchased for use at NSHS conform to specified requirements. NSHS has limited contracting authority. Any items that exceed NSHS authority are subcontracted to Fleet and Industrial Supply Center (FISC), Washington Detachment, Washington Navy Yard and the FISC Philadelphia, or the Naval Medical Logistics Command in Frederick, MD. Contracts for leases and purchases of computers are administered through Naval Medical Information Management Command, Bethesda, MD.

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NSHS is guided by and follows the Federal Acquisition Regulations (FAR) for mandatory and optional sources of supply and service directly associated with the Command's ability to meet requirements. Files, regulations, and procedures are maintained in the Materials Management Department.

Products/services purchased for use in conjunction with NSHS products/services satisfy all current government safety and environmental regulations.

Prior to placing orders, NSHS will ensure that purchase orders are reviewed against requirements.

Purchasing information will describe the product/service to be purchased, including where appropriate:

Requirements for approval of product/service procedures, processes and equipment.  
Requirements for qualification of personnel.  
Quality Management System requirements.

### **7.4.3 Verification of Purchased Product**

NSHS will ensure that purchased product/service meets specified purchase requirements through inspection or other activities.

When verifying purchased product/service at the supplier's premises (source inspection), the verification arrangements and the method of product release are defined, documented, and controlled.

If specified in the contract, NSHS customers have the right to verify product conformity at the supplier's facility.


Customer verification does not preclude subsequent rejection by the customer.  
Customer verification is not sole evidence of effective control of quality.

## **7.5 Production and Service Provision**

### **7.5.1 Control of Production and Service Provision**

NSHS plans and carries out production and service provision under controlled conditions. Controlled conditions include, as applicable:

The availability of information that describes the characteristics of the product.  
The availability of work instructions.  
The use of suitable equipment.  
The availability and use of monitoring and measuring devices.  
The implementation of monitoring and measurement.

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The implementation of release, delivery, and post-delivery activities.

### 7.5.2 Validation of Processes for Production and Service Provision

There are no NSHS processes where the resulting output cannot be verified. Should such processes be identified, NSHS will address each appropriately and comply with all QMS requirements.

### 7.5.3 Identification and Traceability

Where traceability is required, NSHS will control and record the unique identification of the product/service. Product data is identified by unique methods controlled within the level 2 and 3 processes.

### 7.5.4 Customer Property

The use of customer consigned materials or customer supplied third party material is controlled within the QMS. Special attention is given to maintenance agreements for customer consigned materials. Any such material that is lost, damaged, or is otherwise unsuitable for use is recorded and reported to the customer.

### 7.5.5 Preservation of Product

NSHS preserves the conformity of product/service during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product/service. Product/service data and training materials are identified by methods within the processes.

## 7.6 Control of Monitoring and Measuring Devices


There are documented procedures to control, verify, and maintain inspection, measuring, and test equipment used to demonstrate the conformance of product/service to the specified requirements.

All test equipment used for product/service verification are identified and verified prior to use and re-verified at prescribed intervals. When test equipment is found to be unacceptable during testing or re-verification activities, the validity of previous test results is assessed. All test equipment is safeguarded against unintended access or changes that would invalidate the verification status of the systems.

Documented procedures define test equipment calibration intervals.

## 8.0 Measurement, Analysis and Improvement



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## 8.1 General

NSHS monitors, measures, analyzes and improves processes needed to:

- Demonstrate product/service conformity using test and/or measurement activities.
- Ensure conformity of the QMS via internal audits.
- Continually improve the QMS effectiveness, including metrics, using customer satisfaction data and management review activities.

## 8.2 Monitoring and Measurement

### 8.2.1 Customer Satisfaction

NSHS is intent on meeting customer expectations and requirements per NSHS-005. Higher authority determines certain customer requirements.

### 8.2.2 Internal Audit

NSHS has a documented, comprehensive system for planning and executing internal quality audits to ensure QMS activities and related results comply with planned arrangements and are effective (NSHS-006).

Audits are scheduled based on the status and importance of the activity, and carried out by personnel not in the direct chain of command of those responsible for the activity being audited. Internal auditors are qualified based on completing an Internal Quality Audit Course, or equivalent experience, and through on-the-job training via a qualified internal auditor. The Management Representative, the NSHS-006 process owner, and/or the NSHS Lead Auditor determine the criteria for auditor qualification.

An annual audit schedule is developed which includes provisions for auditing both directorate and inter-directorate procedures. The audit plan ensures that each process is audited a minimum of once every three years.


Internal quality audit results are documented and managed per NSHS-006.

Process owners take timely corrective action per the Corrective and Preventive Action Process (NSHS-004) on audit findings as needed. Follow-up audits are then performed to verify and record the actions taken.

### 8.2.3 Monitoring and Measurement of Processes

NSHS will apply methods for monitoring and, where applicable, measuring QMS processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective and/or preventive action will be taken, as appropriate, to ensure conformity of the product/service.



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## 8.2.4 Monitoring and Measurement of Products/Services

NSHS will monitor and measure the characteristics of products/services to verify requirements are fulfilled. This will be carried out at appropriate stages of the product/service realization per NSHS QMS processes.

Evidence of conformity with the acceptance criteria will be maintained. Records will indicate the person(s) authorizing release of product/service.

Product release and service delivery will not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by appropriate NSHS staff, and/or the customer.

## 8.3 Control of Nonconforming Product/Service

Product/service that does not conform to specified requirements is prevented from unintended use. Controls are provided for identification, documentation, evaluation, segregation, and disposition of nonconforming product/service, and for notification of the functions concerned.

The responsibility for review and authority for the disposition of nonconforming product/service is defined. Nonconforming product/service is reviewed per documented processes, testing plan, or implementation plan and may be:

- Reworked to meet the specified requirements.
- Accepted with or without repair by concession.
- Re-graded for alternative applications.
- Returned to the supplier.
- Scrapped or deleted.


Where required by the contract, the proposed use or repair of product/service which does not conform to specified requirements is reported to the customer or customer's representative for concession.

The description of a nonconformity that has been accepted, and of repairs, is recorded to denote the actual condition.

NSHS maintains documented procedures outlining the process used to control reworked product/service, including notifying customers of reworked material as appropriate.

NSHS approves substitutions to supplier materials received by NSHS. Incoming material specification changes that affect customer product/service specifications are approved only after obtaining agreement from the customer.

Records of the nature of non-conformities and any subsequent actions taken, including concessions obtained, will be maintained.

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When nonconforming product/service is corrected, it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product/service is detected after delivery or use has started, NSHS will take action appropriate to the effects, or potential effects, of the nonconformity.

## 8.4 Analysis of Data

Performance data is used throughout NSHS to better ensure the ability to meet customer expectations. The Management Review process includes analyzing this data for problem solving/prevention. The following are examples of data used in this manner:

- Customer satisfaction.
- Conformance to product/service requirements.
- Process and product/service characteristics and trends.
- Supplier performance.

NSHS determines, collects and analyzes appropriate data to demonstrate QMS suitability and effectiveness, and to determine where continual improvement efforts can be made. Trends in NSHS data (i.e. productivity, efficiency, effectiveness, and cost of quality) are analyzed and compared to overall strategic goals and objectives. Key product/service features are included in analysis and if deficiencies are noted, action is taken to correct them and ensure customer satisfaction.

## 8.5 Improvement


### 8.5.1 Continual Improvement

NSHS pursues continual improvement in all aspects of performance, with emphasis on customer-perceived quality, cost, and delivery factors, through the use of the Quality Policy, Quality Objectives, audit results, data analysis, corrective and preventive actions and Management Review:

- The ESC monitors selected objective performance indicators.
- Long-term performance history is periodically evaluated and trends are analyzed.
- Targets are established based on performance. Priority is given to indicators that do not attain satisfactory customer performance levels.
- Performance is monitored against planned targets. Formal corrective action is initiated when planned targets are repeatedly missed.
- Performance indicators are updated as appropriate.

### 8.5.2 Corrective and Preventive Action

NSHS will take action to eliminate the cause of nonconformities and potential nonconformities in

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order to prevent recurrence/occurrence.

A documented process (NSHS-004) has been established to define requirements for:

- Reviewing a non-conformity (including customer complaints).
- Determining the cause of the nonconformity or potential nonconformity.
- Evaluating the need for action to ensure that the nonconformity does not occur/recur.
- Determining and implementing action needed.
- Recording the results of action taken.
- Reviewing corrective and preventive action taken.

## 9.0 Summary of Changes

<i>Version</i>	<i>Description</i>	<i>Date</i>
01	Initial issue of procedure	17 MAY 01